

Appln No.: 09/944,326  
Amendment Dated: May 29, 2006  
Reply to Office Action of April 4, 2006

#### REMARKS/ARGUMENTS

This is in response to the Office Action mailed April 4, 2006 for the above-captioned application.

Claim 1 has been amended to refer to a sequence comprising the SEQ ID NO: 4 consistent with the Examiner's interpretation of the word "has."

Claims 28 and 29 have been added. These claims specifically state that the term oligonucleotide refers to a composition having a length of 18 to 21 bases, or 21 bases, consistent with the number of bases in sequences referred to as oligonucleotides in the specification. Claim 30 states that the oligonucleotide consists of SEQ ID No.: 4.

The Examiner has maintained the rejection for obviousness-type double patenting over claim 1 of US Patent No. 6,900,187. As previously noted, the '187 patent is later filed, and therefore a two way analysis is appropriate. In other words, an obviousness type double patenting rejection cannot be made if the subject matter of the '187 is a non-obvious improvement over the claims of this application. This requires consideration of obviousness, not merely of a genus-species relationship.

In the present case, the disclosure of the sequence that is common to the claims of this application (Seq. ID No. 4) and claim 1 of the '187 patent was published in the PCT counterpart of this application more than a year before the filing date of the '187 patent. As such, it was clearly prior art and was of record and considered by the Examiner in that case. To allow claim 1 of the '187 patent, the Examiner in that case must have determined that claim 1 was both novel and not obvious. Here, the Examiner asserts a different conclusion, but has offered no reasons why the standard of obviousness is met. Thus, Applicants submit that there is no basis for the obviousness-type double patenting rejection.

It is further noted that in response to the previous argument, the Examiner has stated that the argument is "not persuasive because no restriction has been made in the instant application or in that of the '187 patent asserting that the unmodified and the modified sequences were patentably distinct." It is respectfully pointed out, however, that the claims to the modified and unmodified sequences have not been presented in the same application. Thus, the absence of a restriction requirement is not relevant and does not relieve the Examiner from making a showing with respect to obviousness. Thus, this rejection should be withdrawn.

The Examiner has also maintained the rejection of claims 1 and 23 under 35 USC § 103 as obvious over the combination of Wong et al and Barrachini. In support of maintaining this rejection, the Examiner argues that the argument that the 1300 bases sequence of could be

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considered a "short nucleotide" and therefore an oligonucleotide if it was compared to something as large as large as 6000 bases. The Examiner has not provided any evidence to suggest that a person skilled in the art has ever interpreted the term oligonucleotide in a manner that would encompass a sequence of 1300 base pairs. Further, while there is some variability in the art in the definition of oligonucleotide, no definition of record refers to any sequence that is this large as an oligonucleotide or defines oligonucleotide as being small relative to something else. In this regard, Applicants enclose an additional set of definitions and references which are inconsistent with the Examiner's position. The Examiner is therefore requested to withdraw the rejection or to provide evidence that the term "oligonucleotide" might be read by the person skilled in the art, when considered in light of the specification, in the manner indicated by the Examiner.

The Examiner also argues that the word "has" is equivalent to the open-ended "comprising" and that the claims therefore do not exclude sequences the size of cDNA. Applicants submit that this argument fails to read the claims as a whole, including the requirement that the therapeutic be an oligonucleotide. That the claims may be open-ended to some extent, does not negate the remaining words in the claim.

The Examiner further argues that the teaching in Wong et al that TRPM-2 "is associated" with various diseases would make it obvious to make a composition to inhibit expression of the gene in order to discover its role. This is clearly at best an invitation to experiment and does not render any particular thing obvious. Indeed, Wong et al does not make it clear that inhibition would have any beneficial effect, and therefore does not suggest making pharmaceutical compositions with a carrier suitable for human administration as claimed.

Applicants note that the Information Disclosure filed March 18, 2005 has not been considered. In the Advisory Action mailed May 25, 2005, the Examiner stated that this IDS had not been considered because no statement under Rule 1.97(e) was filed. Subsequently, however, the Examiner reopened prosecution, which meant that no requirement for a statement existed. Furthermore, Applicants paid the fee for the submission of the disclosure statement. Thus, Applicants submit that this Information Disclosure Statement and the references cited therein

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should now be considered. For the Examiner's convenience, a replacement copy of the PTO 1449 is attached.

Respectfully Submitted,

  
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Attachments:

PTO 1449 as filed Mar 21, 2005